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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,648

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Mark A. Rydell

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EXAMINER

STEWART, ALVIN J

ART UNIT

PAPER NUMBER

3774

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/562,648

**Applicant(s)**

RYDELL ET AL.

**Examiner**

Alvin J. Stewart

**Art Unit**

3774

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 19, 20, 22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 19, 20, 22, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/03/11 has been entered.

### ***Statement under 37 CFR 3.73(b)***

Regarding the 3.73 (b) statement, the Applicant's representative remarks disclose that the Statement under 37 C.F.R. §3.73(b) was submitted but no attachment to the §3.73(b) have been found in the RCE filed on 03/03/11. In order to overcome this, the Applicant's representative must submit the proper statement.

The statement under 37 CFR 3.37(b) is defective. The chain of title from the inventor's to the current assignee is defective. The applicant's representative must enter in column B, column 1 first the inventors to Adv. Bio-Surfaces, then column 2, Adv. Bio-Surfaces to ABS Corp. and col. 3 from ABS Corp. to MEMometal tech. Correction is required. A new 3.73(b) is required.

### ***Specification***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

***Response to Arguments***

Applicant's arguments filed 03/03/2011 have been fully considered but they are not persuasive.

The Examiner maintains the same rejection used in the Final Rejection filed on 10/13/2010. The Applicant's representative has not entered new limitations describing the application. The Applicant's representative is just arguing the Examiner's rejections.

The amendment to the specification has been accepted and entered.

**Parks, et al rejection:**

**Upsher-Smith Laboratories, Inc. v. PamLab, LLC, 412 F.3d 1319, 1322 (Fed. Cir. 2005)**

**Case Law argument:**

First, the Applicant's representative is interpreting a short paragraph (as shown in page 6 of the applicant's remarks) of an extensive Federal Circuit Court argument with respect to the above Case Law. The Applicant's representative argues that one element of the Parks reference cannot be selectively removed from the other components as a basis for a rejection under 35 U.S.C. §102(e). The Applicant's representative discloses that the multi-component implant of Parks cannot be an infringement of applicants' presently claimed invention drawn to a monolithic implant. The Applicant also argues that the Federal Circuit decisions have repeatedly required that anticipation is established only if all of the elements as stated in a patent claim are identically set forth in a single prior art reference. Disclosure of each element is not quite enough.

Regarding the above paragraph, the Examiner disagrees with the Applicant's representative point of view. The MPEP 2123 section I discloses that patents are relevant as

prior art for all they contain. “The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems to which they are concerned. They are part of the literature of the art, relevant for all they contain”. *In re heck*, 699 F. 2d 1331, 1332-33 216 USPQ 1038, 1039 (Fed. Cir. 1983).

Second, the Applicant’s representative disagrees with the Examiner’s point of view because the Parks, et al reference teaches other parts, such as elements 60 & 40 and not only a single element as disclosed by the Applicant’s representative arguments. The Examiner wants to remind the applicants representative (as mentioned in the previous Office Action) that by just adding the word “monolithic” at the preamble of independent claim 1 and the transitional phrase “consisting essentially of a monolithic tibiotalar implant” have not been interpreted as an exclusive or closed-ended phrase. Nowhere in the written specification exclude other parts, such as elements 60 or 40 and there is no evidence that the presence of other parts would materially affect the basic and novel characteristics of that one single piece. See Case Law *In re Herz*, 537 F. 2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976), as disclosed in the MPEP section 2111.03. The above section discloses that the phrase “consisting essentially of” will occupy a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising format because for the purposes of searching and applying prior art the absent of a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising”. See *PPG*, 156 F. 3d at 1355, 48 USPQ2d at 1355 and also, *AK Steel Corp. v. Sollac*, 344 F. 3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003).

Third, as mentioned above, the Examiner interpreted the word "monolithic" as a structure composed of a single piece. Meaning that the structure is not made of two pieces or more and connected with each other by adhesive, a weld, a bolt, screws, etc... The meaning of the word: monolithic in the Merriam-Webster dictionary is: ---formed from a single crystal", ---formed or composed of material without joints or seams---. The Examiner has taken this meaning from the Merriam\_Webster dictionary because the original written specification has fail to clearly disclose a specific meaning on the word "monolithic" and/or in the phrase "consisting essentially of".

The Examiner believes that the specification is still absent of a clear indication in the specification or claims of what the basis and novel characteristics actually are. For example, in page 2, lines 27-30 of the Applicant's specification disclose that the device can be made of a composite or monolith structure (now the applicant's representative trying to delete the word "composite". Therefore, the word "monolithic" does not provide any criticality or provide a clear indication of what the basic and novelties of the invention are. The Examiner maintains the same interpretation as the previous Office Action.

Four, the Applicant's representative argues that the Parks et al reference is a multi-component system and because of the above statement the prior art cannot be used. The Examiner wants to point out that through out the specification of this application, shows an interpositional arthroplasty system capable to be positioned in the tibiotalar and/or subtalar joints (see Figure 1).

Fifth, the Examiner believes that the Applicant's representative fails to provide evidence that the presence of only element (50) of the Park et al reference would materially affect the

basic and novel characteristics of the claimed invention. Even the Park et al implant can be made of the same materials as the claimed invention (see col. 10, lines 35-44).

Finally, the Applicant's representative discloses that element 50 of the Parks et al reference is not shaped to be positioned against a tibia and Parks et al requires a tibial component which is affixed to a prepared distal tibial surface. The Examiner finds those arguments moot because 1) the Applicant's representative is not positively claiming the method of installation of the implant, 2) the claims are not positively claiming the arguments made in the last paragraph of page 7, 3) the Parks et al implant is clearly capable of performing the argued steps and 4) the claimed invention also disclose tools used to prepare the patient's distal tibial end so the implant 112 can be inserted (see paragraphs 28-30).

Regarding the new limitations regarding the bead, Parks et al clearly discloses the beads at each end of the implant.

The Applicant's representative argues that element 50 of the Parks, et al reference can not be used without the other two elements 40 & 60. As mentioned in the previous Office Action element 50 is a single monolithic piece and is perfectly capable of being used with the natural articulating surface of the patient's tibia.

Regarding the limitations disclosing that the "tibia being allowed to articulate across the first major surface"(claim 22). The Examiner wants to remind the Applicant's representative that those limitations are just functional language and the new entered paragraph "tibia being allowed to articulate across the first major surface" filed on 04/09/10 does not add any structure limitations to the claim. The Examiner has to only find a reference capable of having a tibia being allowed to articulate across the first mayor surface no matter if the articulation is not 100%

efficient as desired by the Applicant. The Examiner just has to find a reference capable of performing the above claimed functional language. The Examiner still believes that the above reference reads on the above claimed functional language.

Regarding claim 22, the Examiner believes that the reference clearly discloses a first mayor surface and a second mayor surface.

For the reasons above, the Examiner believes that the rejection is proper. In order to overcome the rejection the Applicant's representative must add more structure limitations that can distinguished the prior art from the patent application.

Regarding claim 25, see element 58 clearly disclosing a bead shaped structure.

Regarding claims 22 and 25 the Examiner has issued a new rejection.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 19, 20, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Parks et al US Patent 7,025,790 B2.

Parks et al discloses an implant (50) having a convex outer surface and a concave inner surface. Wherein the inner surface comprises external structures such as integral bead (see col. 9, lines 61-63 and col. 10, lines 14-18).



Regarding claim 2, the one or more additional external structures can be interpreted as the second bead (58) and element 54(a).

Regarding claim 3, see Fig. 15. All the parts are integral. The term integral was held not to be limited to a fabrication of the parts from a single piece of material, but was inclusive of other means of maintaining the parts fixed together as a single unit. In re Larson et al., 340 F 2d 965, 144 U.S.P.Q. 347 (C.C.P.A. 1965). « integral is sufficiently broad to embrace constructions united by such means as fastening and welding. In re Hotte, 475 F 2d 644, 177 U.S. P.Q. 326 (C.C.P.A. 1973).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-7 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parks et al US Patent 7,025,790 B2 in view of Mansmann US Patent 6,132,468.

Parks et al discloses the invention substantially as claimed. However, Parks et al does not an implant made of polyurethane.

Mansmann disclose an implant capable of having an articulating implant made of polyurethane for the purpose of a biocompatible and relative soft material (see col. 22, lines 63-67 and col. 23, lines 1-5).

It would have been obvious to one having ordinary skill in the art to change the material property of the Parks et al reference with the polyurethane property of the Mansmann reference in order to have a biocompatible and relatively soft material.

Regarding claims 5-7, It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polyethylene material of the Parks et al reference with the polyurethane material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 7, because the Mansmann reference teaches a polyurethane material, the Shore hardness of the polyurethane will be inherently similar of what is claimed in claim 7.

Regarding claim 25, the Examiner interpreted the hard and soft segments as follow: Parks et al disclosed two cross-sectional areas, for example, thinner cross-section (element 54) and thicker cross-section (58). Because cross-section (58) is thicker than cross-section (54), then the Examiner is interpreting that the hard segment is element 58 and the soft segment is element 54.

NOTE: in order to overcome the rejection above, the Applicant's representative must add the limitations that the hard and soft segments are made of different polyurethane compositions as shown in paragraph 47 of the application.

Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parks et al US Patent 7,025,790 B2 in view of Kopylov et al US Patent 6,814,757 B2.

Parks et al discloses the invention substantially as claimed. However, Parks et al does not disclose an implant having a talus surface substantially free of anchoring portions.

Kopylov et al discloses an implant having a bone surface free of anchoring portions for the purpose of having a similar surface as the surface the implant is trying to substitute (see col. 4, lines 18-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the anchoring portion of the Parks et al reference with the surface free of anchoring portions of the Kopylov et al reference in order to have an implant with a precise bone surface to resemble as much as possible to the natural contour of the articulation surface to avoid excess cutting of the bone.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/  
Primary Examiner, Art Unit 3774

April 29, 2011.